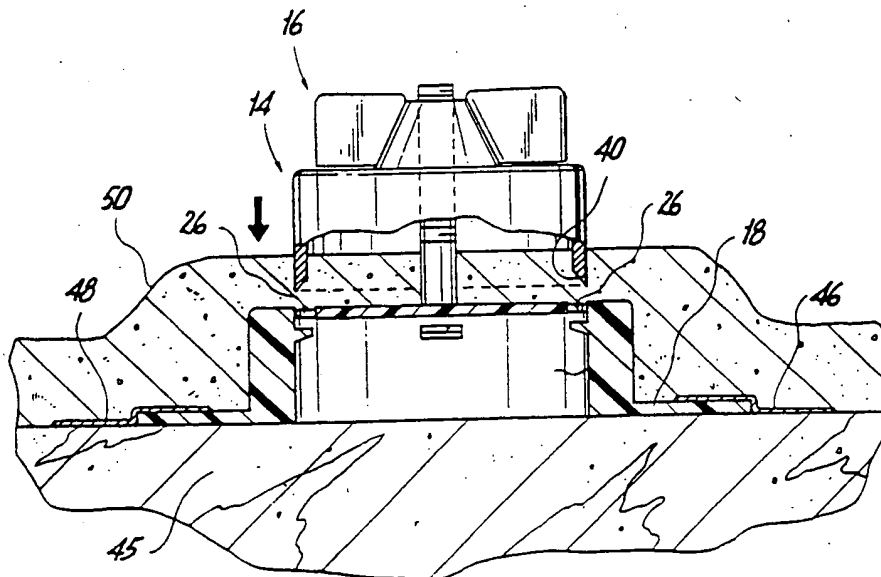


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61F 15/02	A1	(11) International Publication Number: WO 98/10729 (43) International Publication Date: 19 March 1998 (19.03.98)
(21) International Application Number: PCT/US97/16341 (22) International Filing Date: 16 September 1997 (16.09.97) (30) Priority Data: 60/026,391 16 September 1996 (16.09.96) US (71) Applicant (for all designated States except US): EXOGEN, INC. [US/US]; 10 Constitution Avenue, P.O. Box 6860, Piscataway, NJ 08855 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): TALISH, Roger, J. [US/US]; 12 Knoll Road, Fairfield, NJ 07004-1212 (US). (74) Agents: CARTER, David, M. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: CAST PUNCH



(57) Abstract

A cast punch and mounting assembly for forming an opening in an orthopedic cast and securing a therapeutic treatment device within the opening adjacent a bone or musculoskeletal injury is provided. The assembly includes a cast punch housing which is fastened to the body surface beneath the cast. The cast punch housing includes a central bore and a guide rod extending outwardly from the central bore. The guide rod extends through the cast. A punch member and a drive member are operably connected to the guide rod and are movable towards the central bore of the cast punch housing to core an opening in the cast above the central bore. The central bore includes engagement structure to releasably secure a therapeutic treatment device within the central bore of the cast punch housing.

CAST PUNCH

BACKGROUND OF THE INVENTION

5

1. Field of the Invention

The present disclosure relates to a cast punch and mounting assembly for a therapeutic treatment device. More specifically, the present disclosure relates to a cast punch and mounting assembly that provides a precisely positioned opening in an orthopedic cast and securely fastens a therapeutic treatment device within the opening at an external location adjacent a musculoskeletal injury.

10

2. Description of the Related Art

The use of ultrasound to therapeutically treat and evaluate bone injuries is known. Impinging ultrasonic pulses having appropriate parameters, e.g., frequency, pulse, repetition, and amplitude, for suitable periods of time and at a proper external location adjacent to a bone injury has been determined to accelerate the natural healing of, for example, bone breaks and fractures. For patients with reduced healing capacity, such as elderly persons with osteoporosis, ultrasonic therapy may promote healing of bone injuries that would otherwise require prosthetic replacement or leave the patient permanently disabled.

15

20

Typically, an ultrasonic delivery system includes an ultrasonic unit having a transducer and a mounting assembly for mounting an operative surface of the transducer against the skin at a fixed position externally of a musculoskeletal or bone injury. Positioning the operative surface of the transducer at the approximate external skin location of the injury optimizes the ultrasonic therapy. If the operative surface of the transducer is not correctly located, the ultrasound received at the injury may be attenuated, resulting in less than ideal healing time of the bone injury.

25

One problem associated with ultrasonic delivery systems is accurately

positioning the transducer of the ultrasonic delivery system with respect to a bone injury when the system is used to promote healing of a bone injury set in a cast. U.S. Patent No. 4,530,360 to Duarte ("Duarte") describes a basic therapeutic device for applying ultrasonic pulses from an operative surface of a transducer placed on the skin to a bone injury. Duarte states that the device may be used in conjunction with a cast by providing a window in the cast directly above the fracture site. U.S. Patent No. 5,003,965 to Talish et al. ("Talish") also describes a therapeutic device having a transducer for applying ultrasonic pulses to a bone injury. Talish suggests incorporating a fixture into the stockinette of a cast prior to applying plaster to the cast. The fixture includes engagement structure to secure the transducer with respect to the cast. However, movement of the stockinette during placement about the bone injury and during application of the plaster about the stockinette may result in inaccurate placement of the fixture and thus inaccurate placement of the transducer with respect to the bone injury.

Accordingly, a need exists for an improved assembly for accurately mounting and positioning a therapeutic treatment device onto a cast that overcomes the above-noted disadvantages, is easy to use, and provides better results in healing musculoskeletal and bone injuries.

SUMMARY OF THE INVENTION

In accordance with the present disclosure, a cast punch and mounting assembly is provided that is capable of accurately coring an opening in a cast and securing a therapeutic treatment device in the opening. The cast punch and mounting assembly includes a cast punch housing having a central bore, a punch member movable towards the central bore, and a drive member operably engaged with the punch member and movable to advance the punch member towards the central bore of the housing. The punch member may include an annular cutting edge that is advanced by the drive member to provide the opening in the cast. A guide member including a threaded guide rod may be provided to align the punch member with the central bore of the housing and to operably engage the drive member.

BRIEF DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view with parts separated of one embodiment of the cast punch and mounting assembly;

FIG. 2 is a top view of the cast punch housing shown in FIG. 1;

FIG. 3 is a perspective view from the bottom of the punch member shown in FIG. 1;

FIG. 4 is a side cross-sectional view of the punch member shown in FIG. 1;

FIG. 4A is a side cross-sectional view of an alternate embodiment of the punch member;

FIG. 5 is a perspective view of a patient's arm having a template positioned to define a predetermined location on the external surface of the arm;

FIG. 6 is a perspective view of the arm shown in FIG. 5 with the cast punch housing shown in FIG. 1 fastened to the predetermined location;

FIG. 7 is a perspective view of the arm and cast punch housing shown in FIG. 6 partially wrapped in an orthopedic cast;

FIG. 8 is a perspective view of the arm and cast punch housing shown in FIG. 6 fully wrapped in an orthopedic cast;

FIG. 9 is a perspective view of the cast punch housing and cast shown in FIG. 8 further including the punch member and drive member shown in FIG. 1 with parts separated;

FIG. 10 is a partial side cross-sectional view of the cast punch and mounting assembly and cast shown in FIG. 9 with the drive member spaced from the punch member;

FIG. 11 is a partial side cross-sectional view of the cast punch and

mounting assembly and cast shown in FIG. 10 with the drive member engaging the punch member and the punch member extending partially through the cast;

FIG. 12 is a partial side cross-sectional view of the cast punch and mounting assembly and cast shown in FIG. 11 with the punch member extending through
5 the cast;

FIG. 13 is a partial side cross-sectional view of the cast punch and mounting assembly and cast shown in FIG. 12 with the cored cast material removed from the opening formed in the cast;

FIG. 14 is a perspective view of the cast punch housing having the guide
10 rod and cover removed and a therapeutic treatment device aligned with the central bore of the cast punch housing;

FIG. 15 is a partial side cross-sectional view of the cast mounting assembly with a therapeutic treatment device releasably secured within the central bore of the cast punch housing; and

FIG. 16 is a perspective view of the cast punch housing and cast shown
15 in FIG. 15 having an opening with a therapeutic treatment device and a cap aligned for insertion into the opening.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20 Preferred embodiments of the presently disclosed cast punch and mounting assembly will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views.

One embodiment of the presently disclosed cast punch and mounting
25 assembly will now be described with reference to FIGS. 1-4. FIG. 1 illustrates the cast punch and mounting assembly shown generally as 10. Briefly, cast punch and mounting assembly 10 includes a cast punch housing 12, a punch member 14 and a drive member 16. Cast punch housing 12 includes a base member 18 having an engagement surface

configured to be supported on a body surface at a location adjacent an injury, e.g., the arm or the leg. A body portion 20 of housing 12 projects outwardly from the base member 18 and is formed with a central bore 22 having a plurality of bayonet locking lugs 21 formed about its inner periphery. (See FIG. 2)

5 Referring to FIG. 2, a removable cover 24 having a plurality of breakaway tabs 26 releasably fastened to the inner wall of the central bore 22 covers central bore 22 of body portion 20. A guide rod 28 aligned with the central axis of central bore 22 extends upwardly from the removable cover 24 away from central bore 22. The guide rod 28 may be formed with screw threads 30 which are dimensioned to engage the drive member 16 (See FIG. 1), although other conventional engagement structure may also be used to interconnect the drive member 16 with the guide rod 28, i.e., a ratchet.

FIGS. 3 and 4 illustrate the punch member 14 which includes a cylindrical body 32 having an open end 34 and a top wall 36 defining a punch chamber 37. An opening 38 formed in the top wall 36 is dimensioned to slidably receive guide rod 28. (See FIG. 1) Cylindrical body 32 includes an annular cutting edge 40. The cutting edge 40 may be a flat or serrated surface, but is preferably a bevelled surface. Although punch member 14 is disclosed as having a cylindrical body 32, the punch member 14 may be formed having any desired shape, i.e., square, rectangular, oblong, but should have a shape that corresponds to the shape of the central bore 22.

20 FIG. 4A illustrates an alternate embodiment of the punch member 14 shown generally as 14'. Punch member 14' includes an obliquely truncated cylindrical body 32' having an open end 34', a top wall 36' and an annular cutting edge 40'. An opening 38' formed in top wall 36' is defined by an inwardly extending annular flange 39' dimensioned to receive guide rod 28 (See FIG. 1). The annular flange 39' prevents punch member 14' from canting when the cutting edge 40 engages the cast material.

25 Referring temporarily back to FIG. 1, the drive member 16 may be a threaded wing nut having threads that engage the screw threads 30 formed on guide rod 28. Alternately, the drive member may be in the form of any other known drive

mechanism, such as a ratchet. As drive member 16 is advanced along guide rod 28 (by rotating wing nut 16 in FIG. 1, for example), a front surface 43 of drive member 16 engages and advances punch member 14 along guide rod 28 towards central bore 22 of cast punch housing 12.

5 Referring to FIGS. 5-13, placement and operation of the cast punch and mounting assembly 10 will now be described. As shown in FIGS. 5 and 6, a template 47 is positioned about a mark 44 made on the skin 45. The mark 44 identifies the external location of a bone fracture or musculoskeletal injury, and may be determined using the method set forth in U.S. Patent Application No. 08/388,971, filed February 15,
10 1995, incorporated herein by reference. The template 42 has a shape that corresponds to the base member 18 of the casting punch housing 12. A tracing is made using the template 47 and the cast punch housing 12 is secured on the tracing with adhesive strips 46 and 48.

Referring to FIGS. 7-9, a cast 50 is applied about the location of the body
15 corresponding to the bone fracture or musculoskeletal injury and about the cast punch housing 12 such that only the guide rod 28 projects through the cast 50. When it is desired to create a hole in the cast 50, the punch member 14 is positioned about the guide rod 28 and the threads of the drive member 16 are engaged with threaded end 30 of the guide rod 28 and the drive members advanced along the guide rod by rotating.

20 As illustrated in FIGS. 9-12, the drive member 16 is rotated to advance the cutting edge 40 of punch member 14 into engagement with the portion of cast 50 covering the central bore 22 of cast punch housing 12. Continued advancement of drive member 16 forces the cutting edge 40 through cast 50 and into engagement with tabs 26 of cover 24 disengaging tabs 26 from housing 12. The bayonet locking lugs 21 prevent
25 the cutting edge 40 from advancing through the central bore 22 and engaging the skin 45 of a patient.

Referring to FIG. 13, the cover 24 which is fastened to the guide rod 28, may be removed from central bore 22 by grasping the threaded end 30 of guide rod 28

or by grasping driving member 16 and pulling the assembly from the central bore 22 in the direction indicated by arrow "B". The cast material 52 cored from cast 50 by punch member 14 is supported on cover 24 within punch chamber 37 and may be removed from cast 50 with cover 24 to provide an opening 54 in the cast 50 for placement of the
5 therapeutic treatment device.

FIGS. 14 and 15 illustrate cast punch housing 12 in association with a therapeutic treatment device 56. The therapeutic treatment device 56 includes a transducer 62 having a shape that corresponds to the shape of the central bore 22 of cast punch housing 12. A plurality of slotted lugs 60 spaced about the periphery of the
10 treatment device 56 are configured to releasably engage bayonet locking lugs 21 extending from the inner periphery of central bore 22. To engage the slotted lugs 60 with bayonet locking lugs 21, transducer 62 is moved in the direction indicated by arrow "A" into central bore 22 of body portion 20. If the locking lugs 21 are vertically aligned with the slotted lugs 60 during insertion of transducer 62 into central bore 22, locking
15 lugs 21 will be deflected into engagement with one of the slots on the lugs 60. If locking lugs 21 are not vertically aligned with the slotted lugs 60 during insertion of transducer 62 into central bore 22, the therapeutic device 56 may be rotated to bring the locking lugs 21 and the slotted lugs 60 into locking engagement to secure the therapeutic treatment device within central bore 22. The transducer 62 should be fixedly positioned with the
20 operative surface 64 adjacent the external location of the bone injury. The operative surface 65 may be coated with a coupling gel 65 before being inserted into the central bore 22 to optimize the ultrasonic therapy. Alternately, a gel bladder may be positioned between the body to be treated and the operative surface of the transducer 62.

Referring now to FIG. 16, a cap 74 is provided to cover the opening 54
25 in the cast 50 when the therapeutic treatment device 56 is not in use. The cap 74 may have slotted lugs similar to those provided on the therapeutic treatment device 56 to secure the cap 74 within central bore 22. Alternately, the cap 74 may have an annular stepped portion 76 that engages locking lugs 21 to secure the cap 74 within the central

bore 22. The cap 74 includes a contact face 78 which maintains pressure on the skin surface 80 when the device 56 is not in use to prevent "window edemas".

It will be understood that various modifications can be made to the various embodiments of the present disclosure without departing from its spirit and scope. For example, various sizes and shapes of the cast punch and mounting assembly are contemplated, as well as various types of construction materials. Also, an integral punch and drive member is contemplated wherein the punch rotates with the drive member as it cores the opening in the cast. Various types of drive mechanisms to advance the punch through the cast are also contemplated. Therefore, the above description should not be construed as limiting the invention but merely as presenting preferred embodiments of the invention. Those skilled in the art will envision other modifications within the scope and spirit of the disclosure as defined by the claims presented below.

WHAT IS CLAIMED IS:

1. A method of providing an opening in a medical wrapping, comprising:
 - providing a punch assembly including a housing having a bore and
 - 5 a punch member having a cutting edge, the punch member being movable into the bore;
 - positioning the punch assembly housing on a body surface to be medically wrapped;
 - applying medical wrapping about the body surface and the punch assembly housing;
 - 10 advancing the punch member towards the bore of the housing to drive the cutting edge of the punch member through the medical wrapping to sever at least a portion of the medical wrapping covering the bore; and
 - removing the severed portion of the medical wrapping from the bore.
- 15 2. An apparatus comprising:
 - a housing having a bore;
 - a punch member having a cutting edge and being movable relative to the bore from a first position spaced from the bore to a second position within the
 - 20 bore; and
 - a guide member operably associated with the punch member and the housing to restrict movement of the punch member to movement between the first and the second positions.
- 25 3. An apparatus according to Claim 2, further comprising a drive member, the drive member being movable into operable engagement with the punch member to advance the punch member from the first position to the second position.

4. An apparatus according to Claim 3, wherein the guide member includes a guide rod, the guide rod extending along the central longitudinal axis of the bore and being fastened to the housing, and the punch member having a central opening configured to slidably engage the guide rod, the punch member being slidable along the
5 guide rod between the first and second positions.

5. An apparatus according to Claim 4, wherein the guide rod has a threaded portion and the drive member has a threaded opening dimensioned to engage the threaded portion of the guide rod, the drive member being rotatable about the guide rod
10 to advance the drive member along the guide rod into engagement with the punch member to advance the punch member from the first position to the second position.

1/9

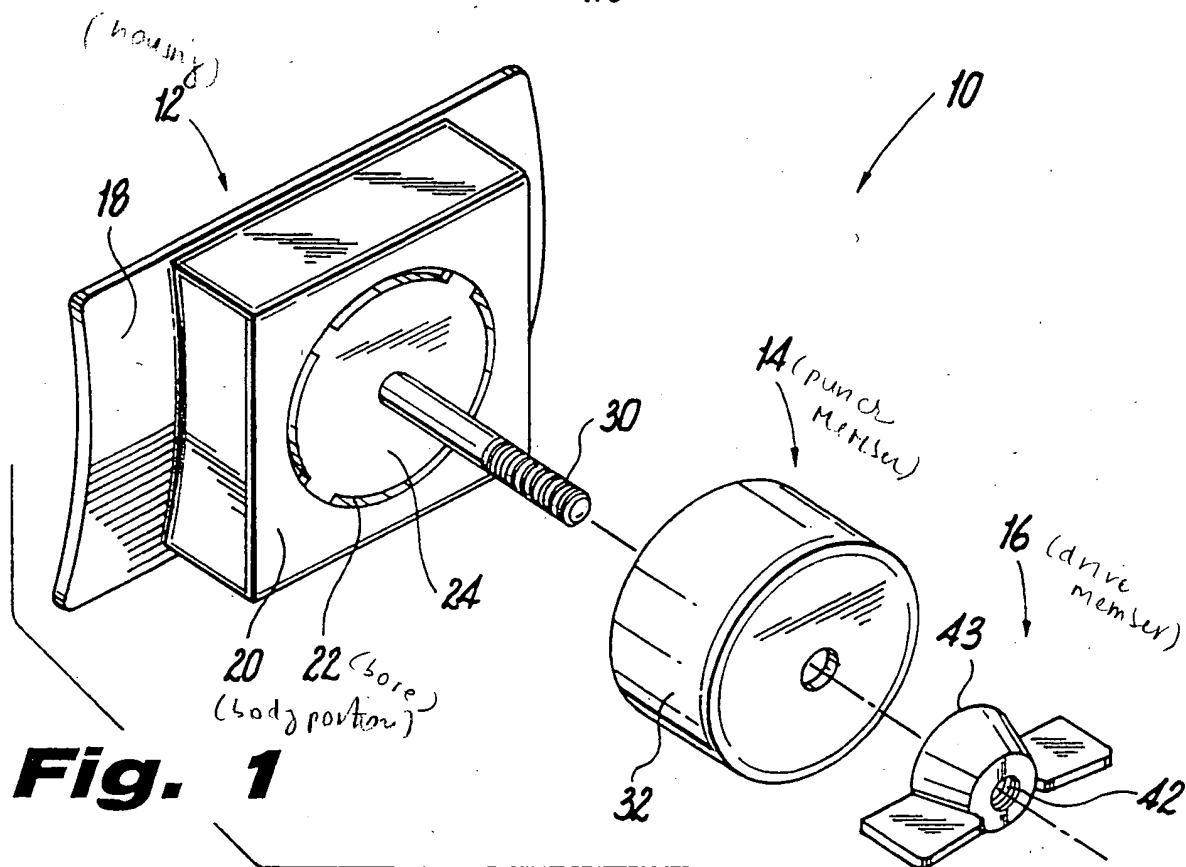
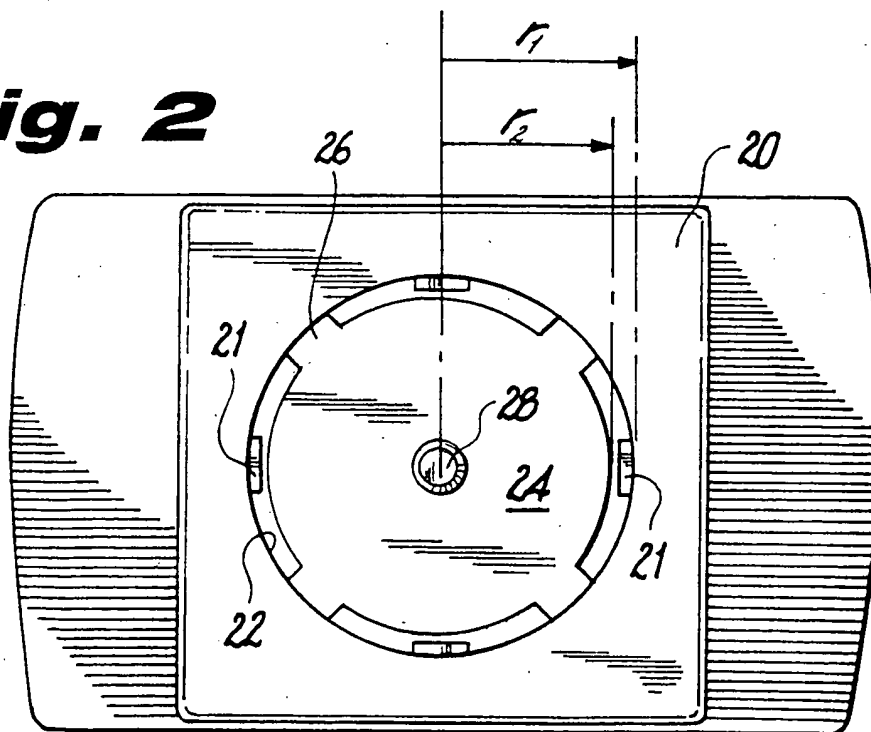


Fig. 2



2/9

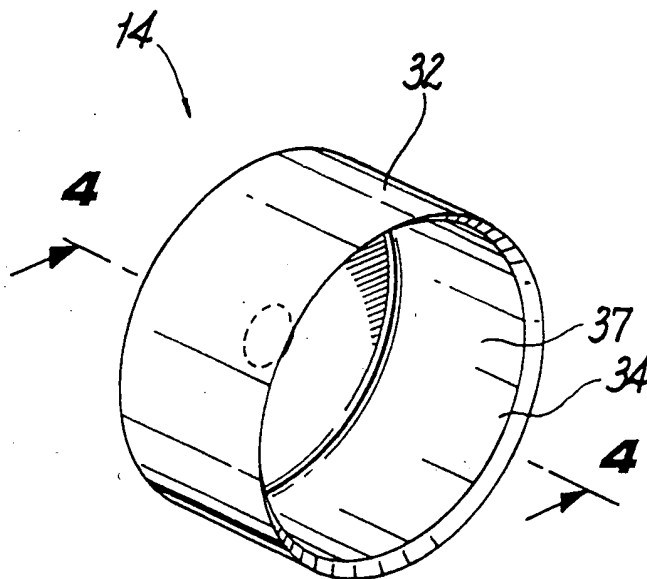


Fig. 3

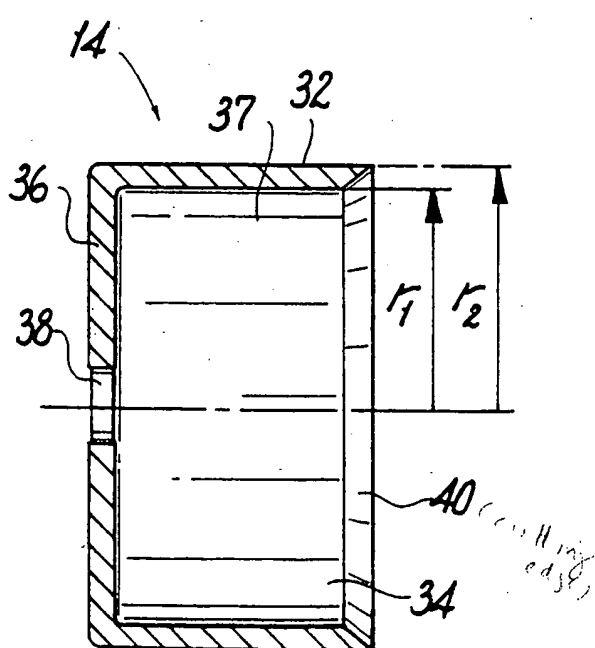


Fig. 4

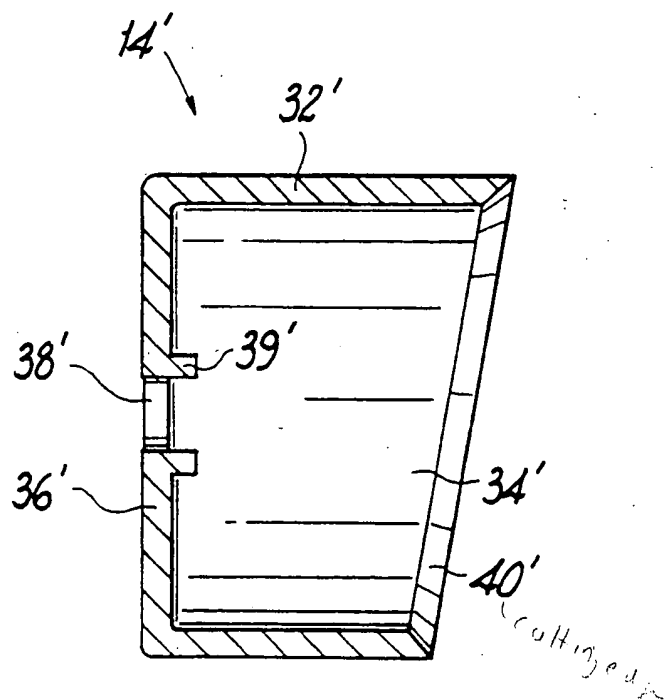
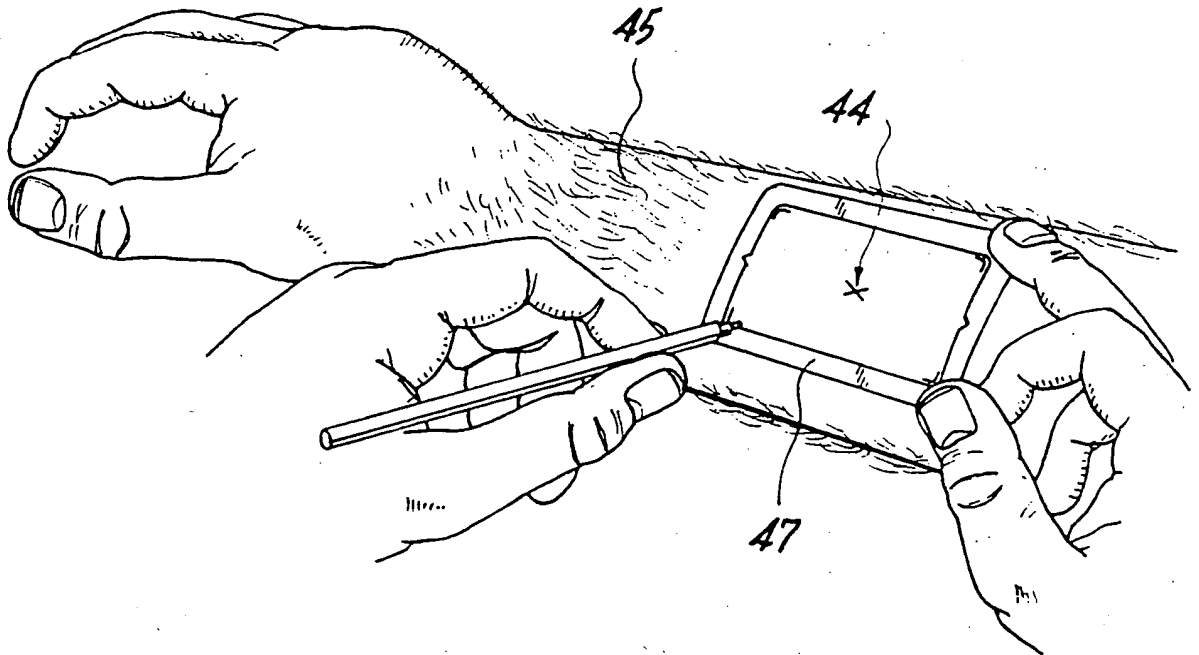
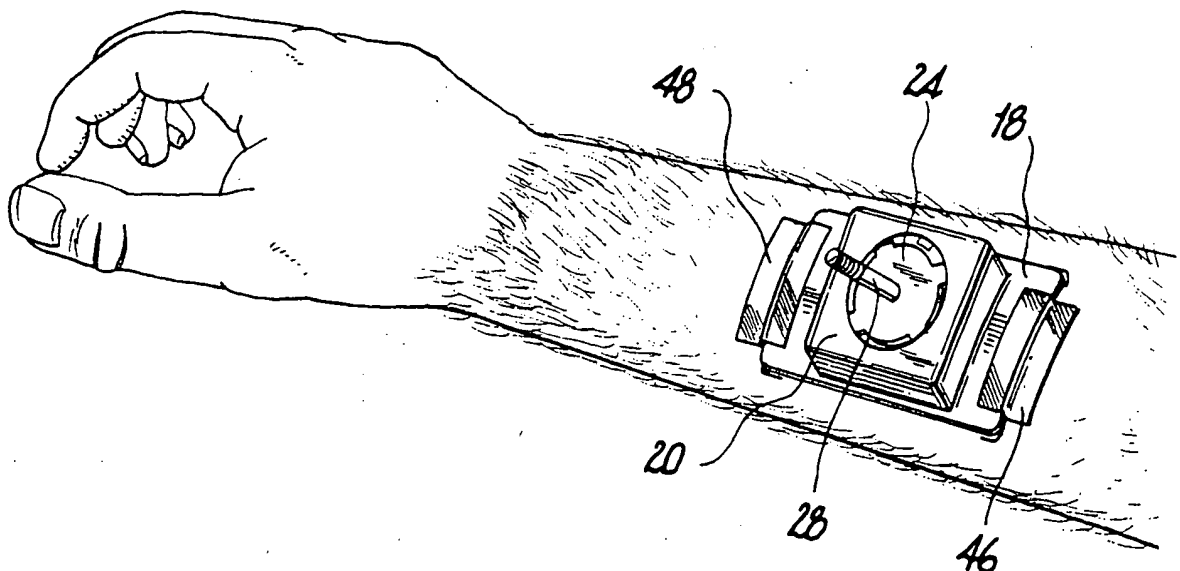


Fig. 4A

Fig. 5**Fig. 6**

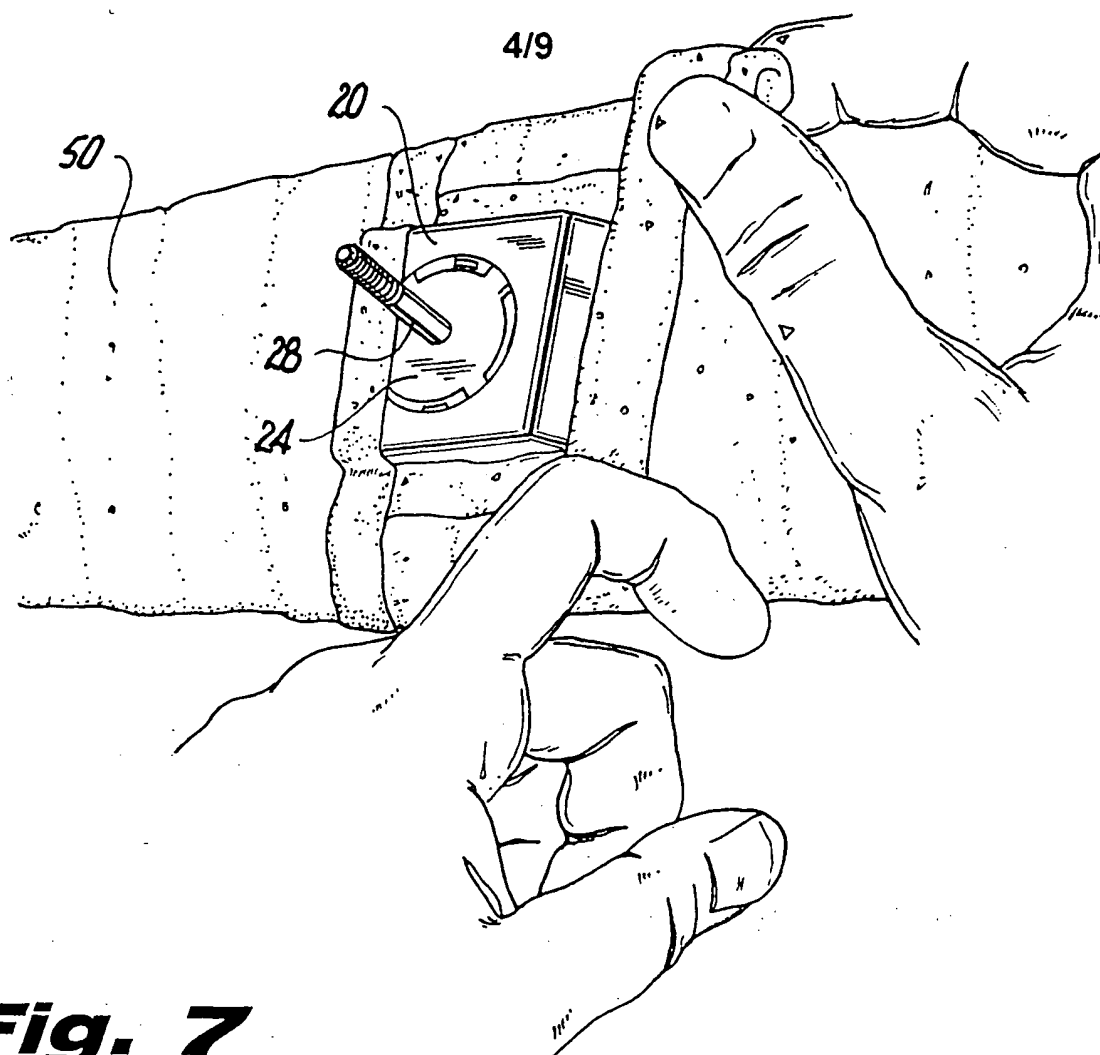


Fig. 7

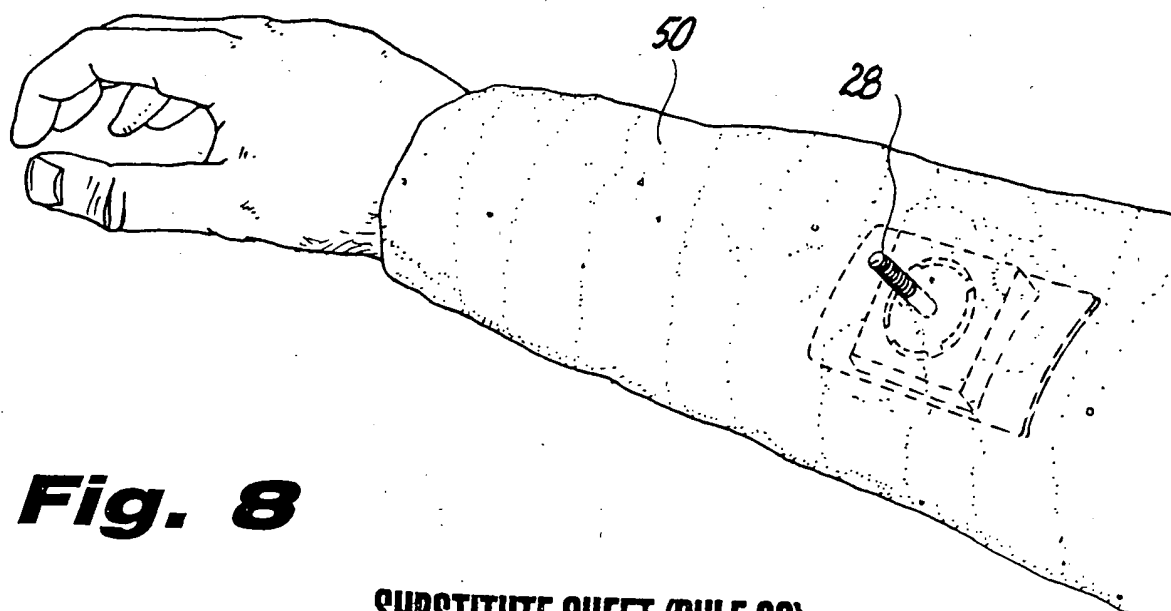
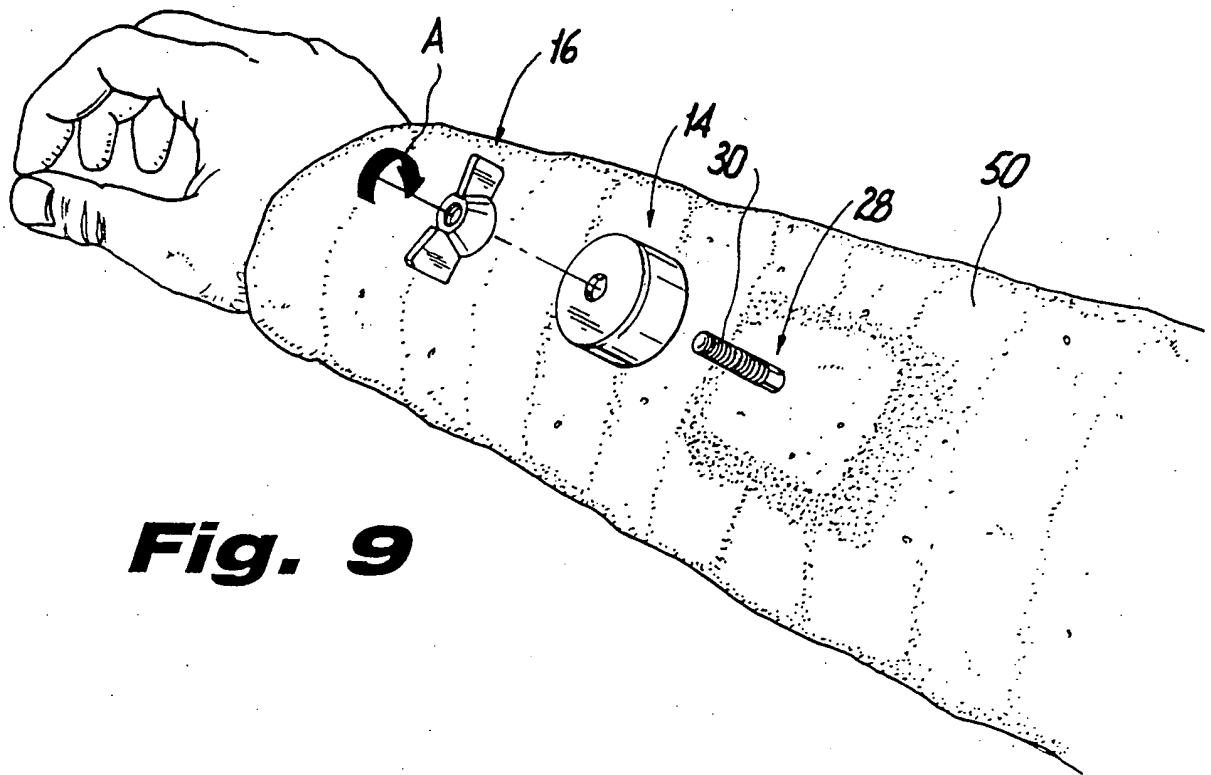
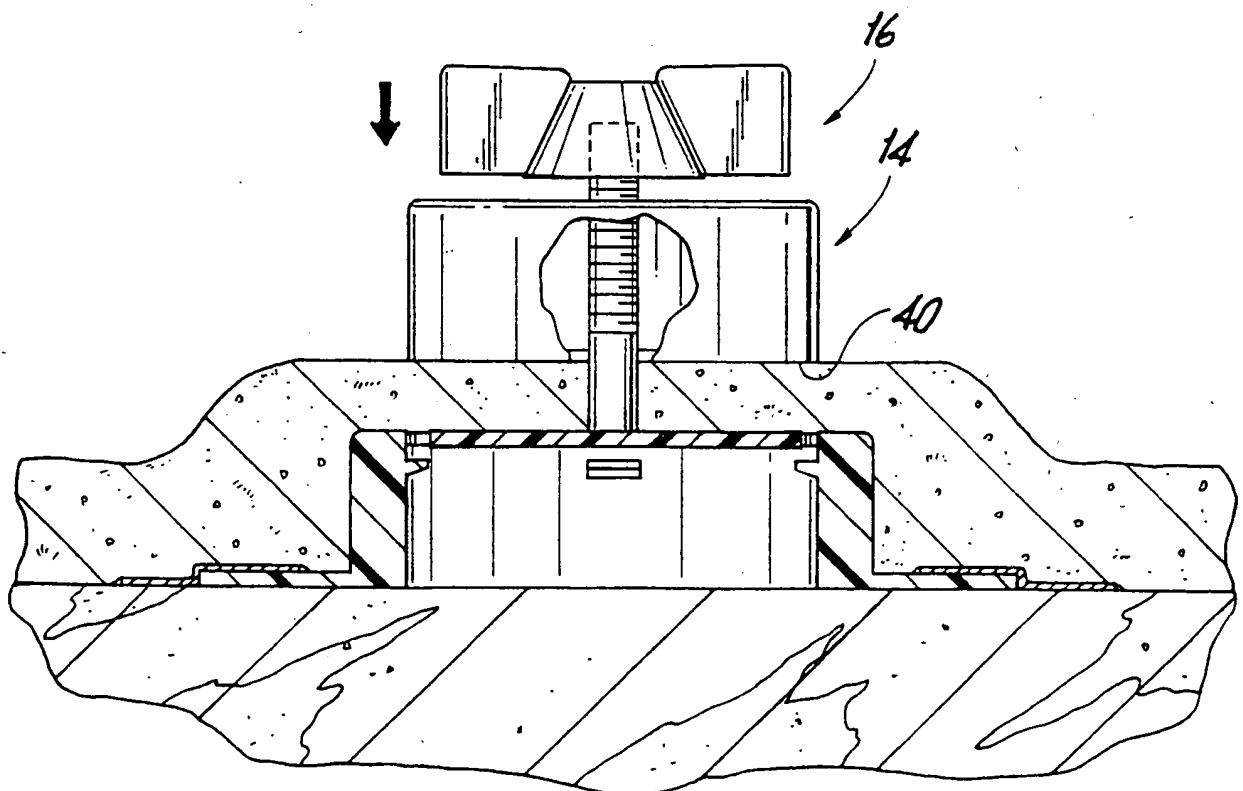
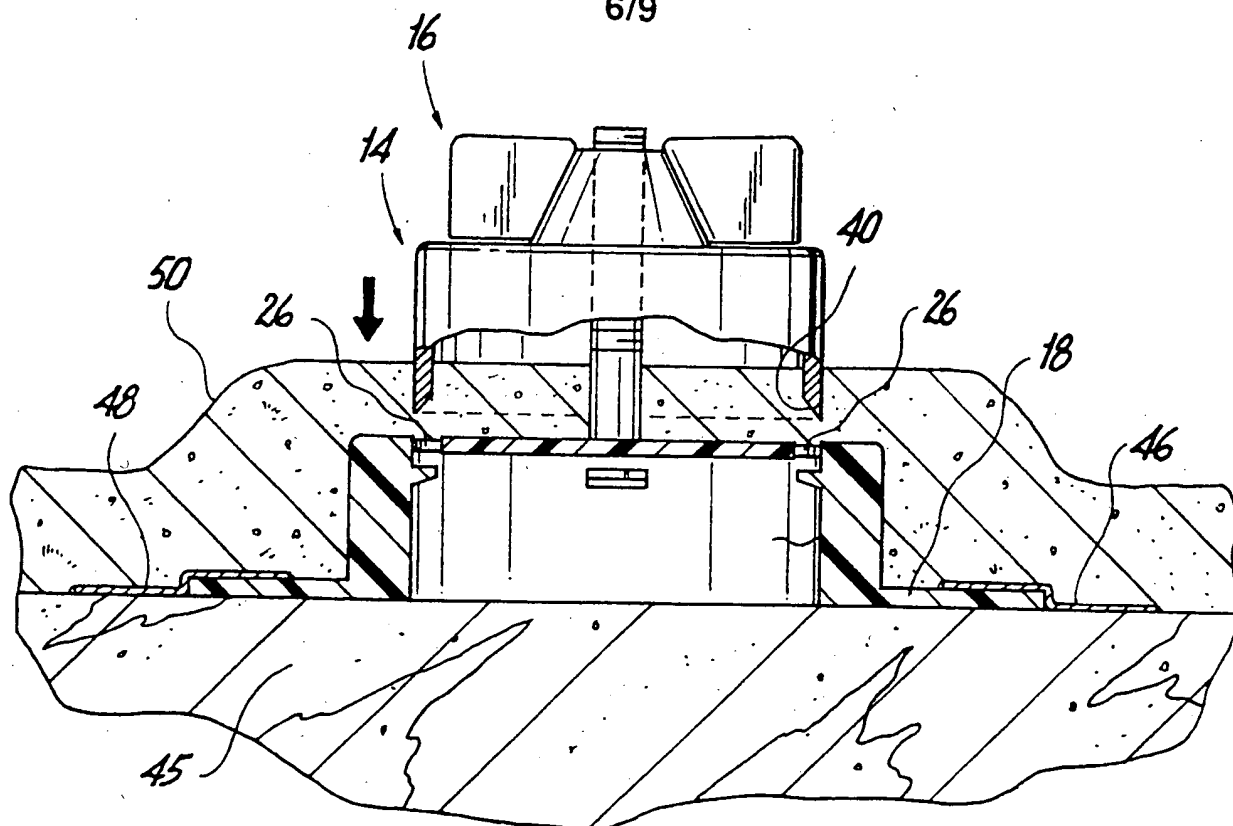
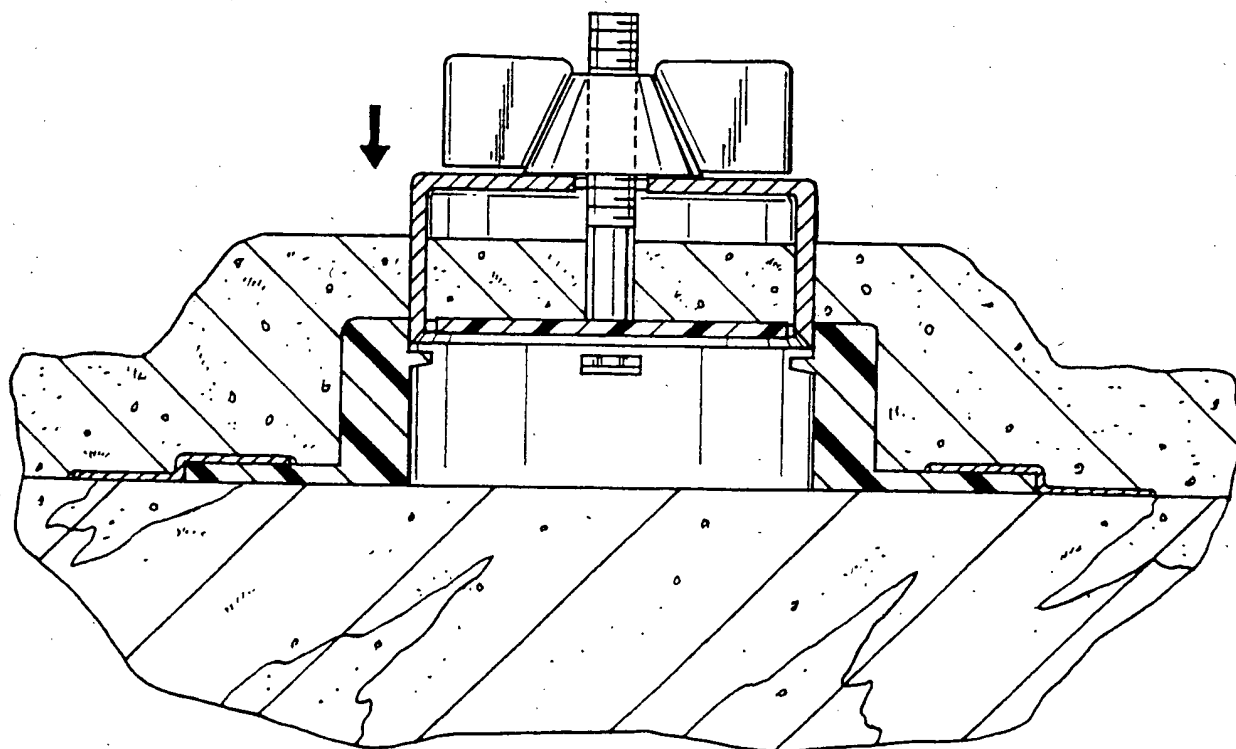


Fig. 8

5/9

**Fig. 9****Fig. 10**

6/9

**Fig. 11****Fig. 12**

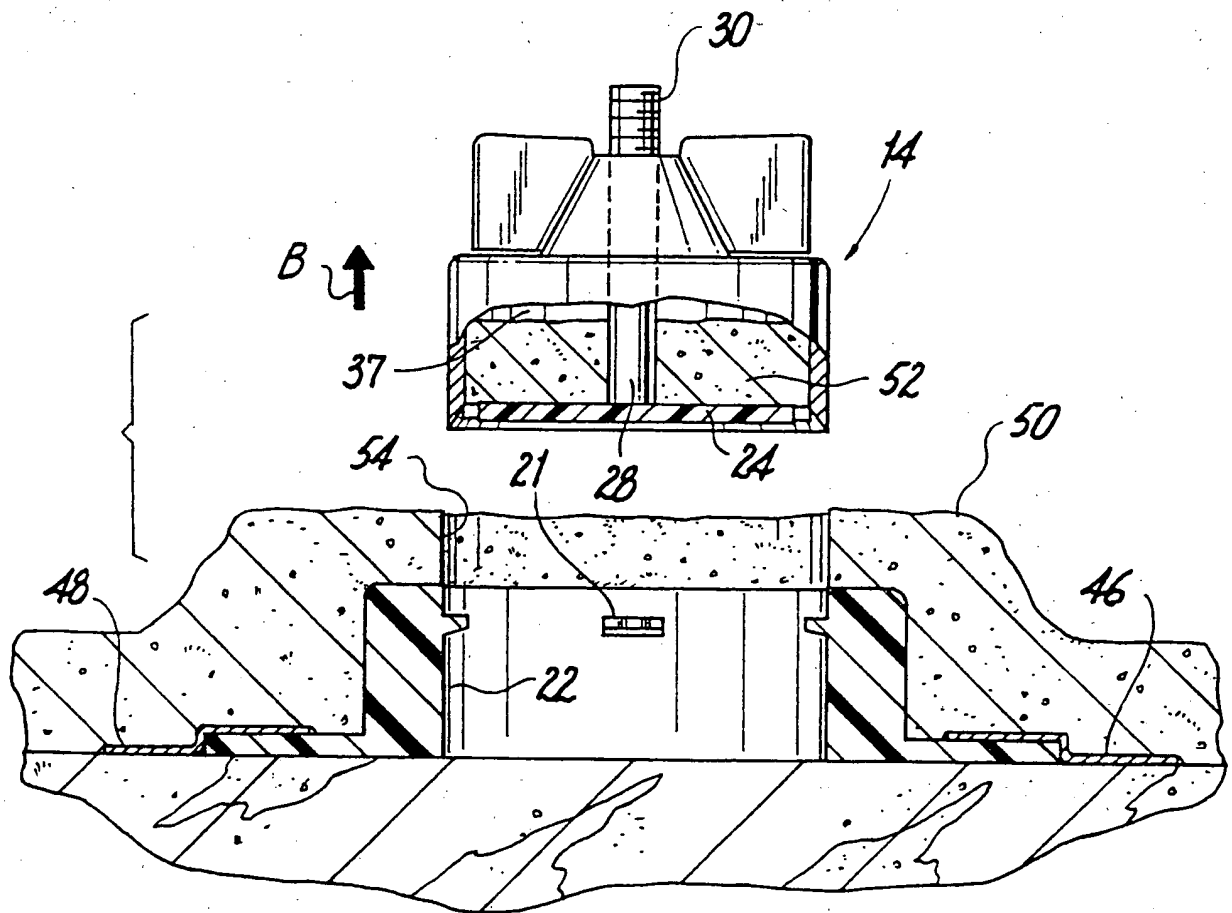
**Fig. 13**

Fig. 14

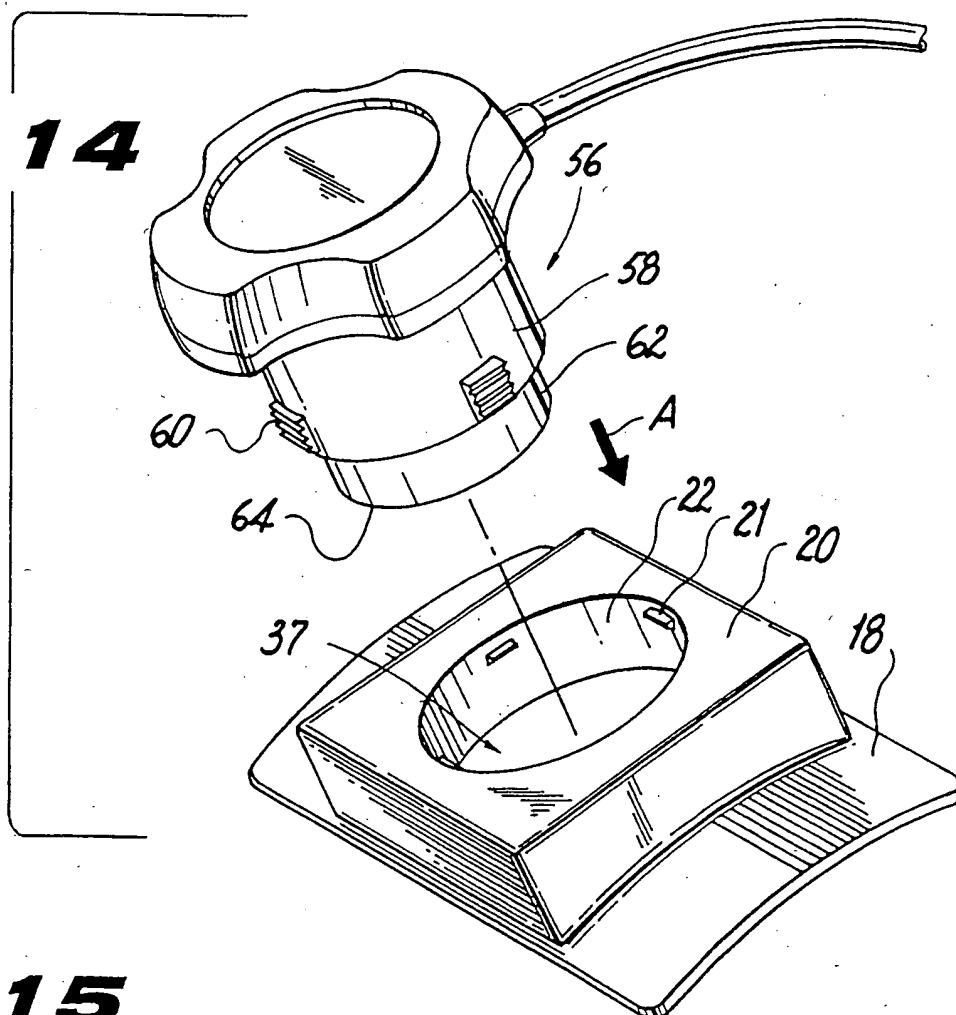
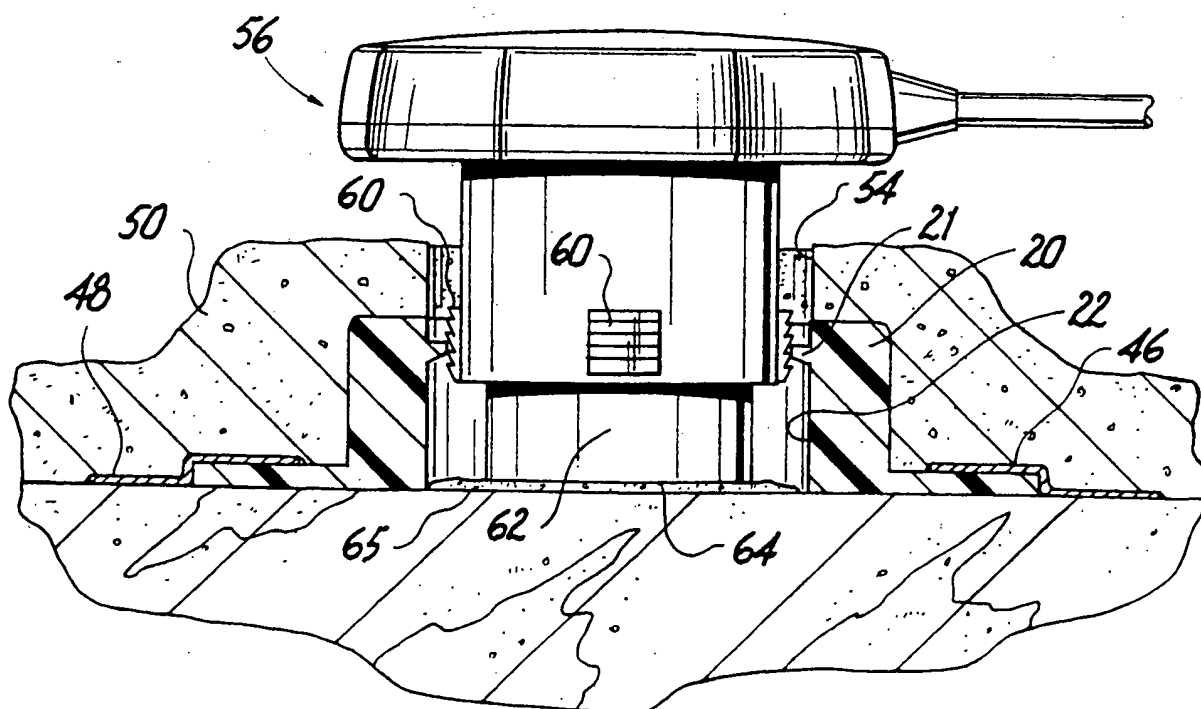
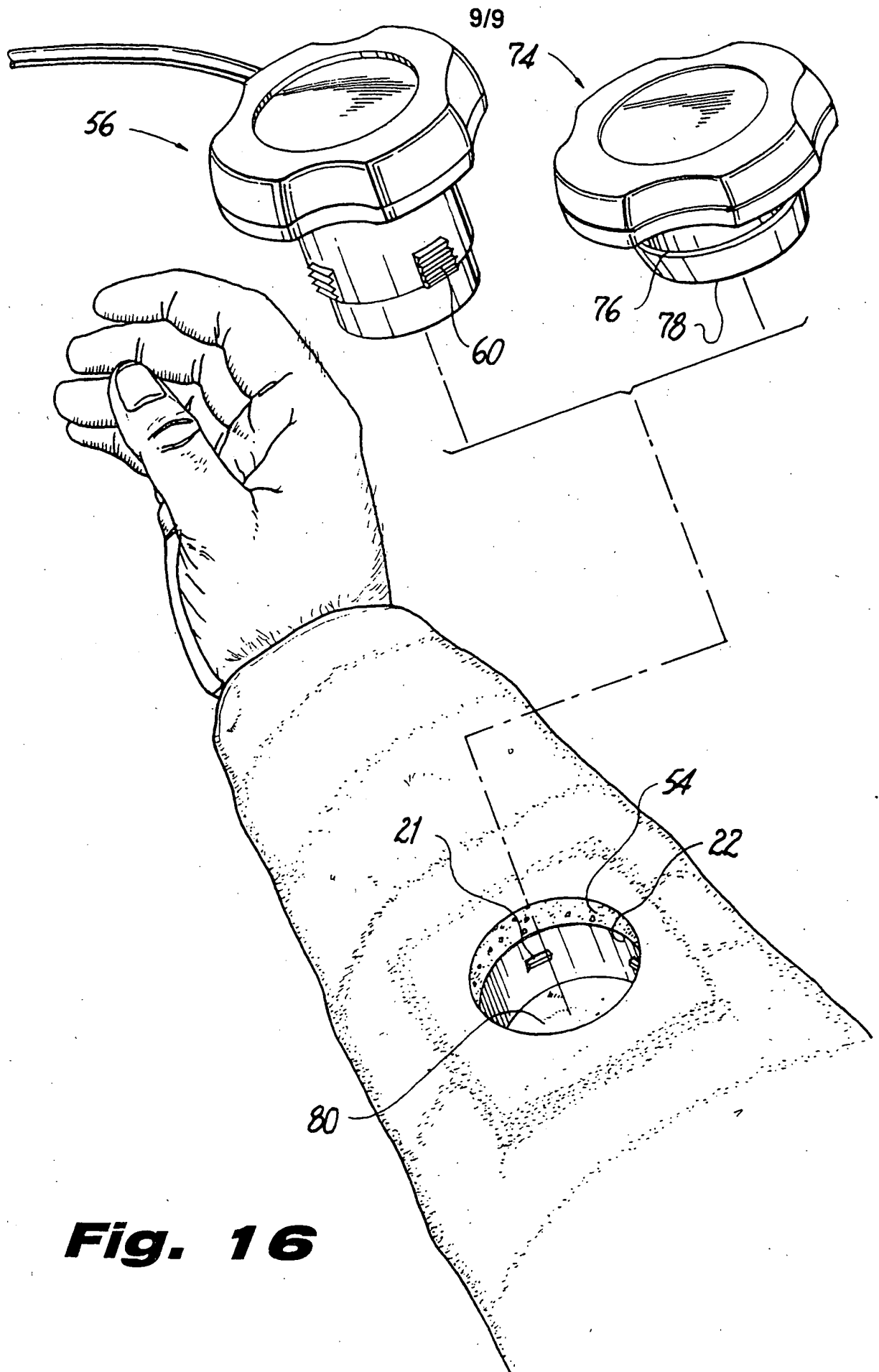


Fig. 15



**Fig. 16**

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☒ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.